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*Admitted only in Maryland
*Admitted only in Virginia
*Practice limited to Federal Agencies

June 8, 2005

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1645

Hand Carry to Examiner J.A. Hines

Re: U.S. Utility Patent Application
Application No. 10/725,009; Filed: December 2, 2003
For: **Method for Freeze-Drying Nucleic Acid/Block Copolymer/Cationic Surfactant Complexes**
Inventors: GEALL
Our Ref: 1530.0620001/EKS/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement under 37 C.F.R. § 1.97(b);
3. Form PTO-1449, 5 pages, listing 51 documents (AA1-AG3, AL1-AM2 and AR1-AT5);
4. One (1) copy of the 22 cited documents (AL1-AM2 and AR1-AT5); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
June 8, 2005
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

EKS/J-H/tis:awt

368358v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GEALL

Appl. No.: 10/725,009

Filed: December 2, 2003

For: **Method for Freeze-Drying Nucleic
Acid/Block Copolymer/Cationic
Surfactant Complexes**

Confirmation No.: 3175

Art Unit: 1645

Examiner: Hines, J.A.

Atty. Docket: 1530.0620001/EKS/J-H

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents, **AL1** to **AM2** and **AR1** to **AT5** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents **AA1** to **AG3**, cited on the attached Form PTO-1449 are not submitted.

The Examiner's attention is directed to the following co-pending, related applications:

U.S. Application No. 09/839,574, inventors Manthorpe *et al.*, filed April 23, 2001, now published as U.S. Publication No. 2002/0019358 A1 (Document **AI2**)

U.S. Application No. 10/360,645, inventors Wolff *et al.*, filed February 10, 2003, now published as U.S. Publication No. 2003/0186913 A1 (Document **AK2**);

U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Publication No. 2003/0191082 A1 (Document **AA3**);

U.S. Application No. 10/127,683, inventors Hobart *et al.*, filed April 23, 2002, now published as U.S. Publication No. 2003/0203863 A1 (Document **AB3**);

U.S. Application No. 10/725,015, inventor Geall *et al.*, filed December 2, 2003, now published as U.S. Publication No. 2004/0162259 A1 (Document **AE3**);

U.S. Application No. 10/748,853, inventor Wheeler, C.J., filed December 30, 2003, now published as U.S. Publication No. 2004/0171572 A1 (Document **AC3**);

U.S. Application No. 10/738,986, inventors Hermanson *et al.*, filed December 19, 2003, now published as U.S. Publication No. 2004/0209241 A1 (Document **AD3**);

U.S. Application No. 09/937,604, inventor Wheeler, C.J., which is the U.S. National Phase of International Appl. No. PCT/US00/08282 (WIPO Publication No. 00/57917 A2) (Document **AN1**), having a 35 U.S.C. §371 date of September 26, 2001;

U.S. Application No. 09/478,457, inventors Wolff *et al.*, filed January 6, 2000, now pending (Document **AR5**);

U.S. Application No. 10/658,688, inventor Hermanson, G.G., filed September 10, 2003, now pending;

U.S. Application No. 10/843,656, inventors Vilalta *et al.*, filed May 12, 2004, now pending;

U.S. Application No. 11/131,479, inventors Luke *et al.*, filed May 18, 2005, now pending; and

U.S. Application No. 60/632,612, inventor Geall, filed December 3, 2004, now pending;

which are directed to related technical subject matter. Copies of co-pending U.S. Application Nos: 10/658,688, 10/843,656, 11/131,479 and 60/632,612 are not provided pursuant to the Waiver of Requirements in 37 C.F.R. § 1.98, *Official Gazette*, October 16, 2004. A copy of co-pending Application No 09/478,457 is provided as the applications are not available electronically via the United States Patent and Trademark Office Image File Wrapper System (IFW). The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits that document **AS4** is in a foreign language. The relevance of document **AS4** may be found in the English language abstract included therein.

The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

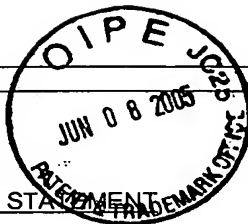
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Registration No. 36,688

Date: 6/8/05

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0620001/EKS/JAHAPPLICATION NO.
10/725,009FIRST NAMED INVENTOR
Geall, A.FILING DATE
December 2, 2003ART UNIT
1645

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|------------------------|-------|-----------|-------------|
| | AA1 | 5,264,618 | 11/23/1993 | Felgner <i>et al.</i> | | | 04/16/1991 |
| | AB1 | 5,459,127 | 10/17/1995 | Felgner <i>et al.</i> | | | 09/16/1993 |
| | AC1 | 5,567,859 | 10/22/1996 | Emanuele <i>et al.</i> | | | 08/09/1994 |
| | AD1 | 5,656,611 | 08/12/1997 | Kabanov <i>et al.</i> | | | 11/18/1994 |
| | AE1 | 5,691,387 | 11/25/1997 | Emanuele <i>et al.</i> | | | 06/03/1996 |
| | AF1 | 5,696,298 | 12/09/1997 | Emanuele <i>et al.</i> | | | 06/02/1995 |
| | AG1 | 5,817,334 | 10/06/1998 | Schmidt <i>et al.</i> | | | 06/06/1995 |
| | AH1 | 5,990,241 | 11/23/1999 | Emanuele <i>et al.</i> | | | 07/08/1997 |
| | AI1 | 5,994,317 | 11/30/1999 | Wheeler | | | 04/09/1996 |
| | AJ1 | 6,251,599 B1 | 06/26/2001 | Chen <i>et al.</i> | | | 11/06/1998 |
| | AK1 | 6,359,054 B1 | 03/19/2002 | Lemieux <i>et al.</i> | | | 01/08/1999 |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL1 | WO 96/04392 A2 | 02/15/1996 | WIPO | | | Yes No |
| | AM1 | WO 96/04932 A1 | 02/22/1996 | WIPO | | | Yes No |
| | AN1 | WO 00/57917 A2 | 10/05/2000 | WIPO | | | Yes No |
| | AO1 | WO 02/00844 A2 | 01/03/2002 | WIPO | | | Yes No |
| | AP1 | WO 97/40839 A1 | 11/06/1997 | WIPO | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|--|
| | AR | 1 | Corveleyn, S. and Remon, J.-P., "Maltodextrins as Lyoprotectants in the Lyophilization of a Model Protein, LDH," <i>Pharm. Res.</i> 13:146-150, Plenum Publishing Corporation (1996) |
| | AS | 1 | Kim, A.I., <i>et al.</i> , "The Physical State of Mannitol after Freeze-Drying: Effects of Mannitol Concentration, Freezing Rate, and a Noncrystallizing Cosolute," <i>J. Pharm. Sci.</i> 87:931-935, American Chemical Society (1998) |
| | AT | 1 | Martini, A., <i>et al.</i> , "Use of Subambient Differential Scanning Calorimetry to Monitor the Frozen-State Behavior of Blends of Excipients for Freeze-Drying," <i>PDA J. Pharm. Sci. Technol.</i> 51:62-67, Parenteral Drug Association (1997) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

| | | |
|---|--|-------------------------------|
| FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 1530.0620001/EKS/JAH | APPLICATION NO. 10/725,009 |
| | FIRST NAMED INVENTOR Geall, A. | |
| | FILING DATE December 2, 2003 | ART UNIT 1645 |

| U.S. PATENT DOCUMENTS | | | | | | | |
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
| | AA2 | 6,482,518 B1 | 11/19/02 | Short <i>et al.</i> | | | 07/30/1999 |
| | AB2 | 6,147,055 | 11/14/2000 | Hobart <i>et al.</i> | | | 03/14/1997 |
| | AC2 | 5,674,911 | 10/07/1997 | Emanuele <i>et al.</i> | | | 06/06/1995 |
| | AD2 | 6,586,409 B1 | 07/01/2003 | Wheeler | | | 03/24/2000 |
| | AE2 | 5,703,055 | 12/30/1997 | Felgner <i>et al.</i> | | | 01/26/1994 |
| | AF2 | 6,670,332 B1 | 12/30/2003 | Wheeler | | | 06/05/1998 |
| | AG2 | 6,399,588 B1 | 06/04/2002 | Hobart <i>et al.</i> | | | 06/04/2002 |
| | AH2 | RE 36,665 | 04/18/2000 | Emanuele <i>et al.</i> | | | 06/02/1998 |
| | AI2 | 2002/0019358 A1 | 02/14/2002 | Manthorpe <i>et al.</i> | | | 04/23/2001 |
| | AJ2 | 2003/0032615 A1 | 02/13/2003 | Felgner <i>et al.</i> | | | 07/26/2002 |
| | AK2 | 2003/0186913 A1 | 10/02/2003 | Wolff <i>et al.</i> | | | 02/10/2003 |

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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
| | AL2 | WO 99/06055 A1 | 02/11/1999 | WIPO | | | Yes No |
| | AM2 | WO 99/21591 A1 | 05/06/1999 | WIPO | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | 2 | Martini, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen state behaviour of amino acids in simulated freeze-drying conditions," <i>S.T.P. Pharma Sci.</i> 7:37-381, Editions de sante (1997) |
| | AS | 2 | Newman, M.J., <i>et al.</i> , "Use of Nonionic Block Copolymers in Vaccines and Therapeutics," in: <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , Bruck, S.D., ed., Begell House, Inc. (1998) |
| | AT | 2 | Oliyai, C., <i>et al.</i> , "Chemical Pathways of Peptide Degradation. VII. Solid State Chemical Instability of an Aspartyl Residue in a Model Hexapeptide," <i>Pharm. Res.</i> 11:901-908, Plenum Press (1994) |

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| FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 1530.0620001/EKS/JAH | APPLICATION NO. 10/725,009 |
| | FIRST NAMED INVENTOR Geall, A. | |
| | FILING DATE December 2, 2003 | ART UNIT 1645 |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|-------------------------|-------|-----------|-------------|
| | AA3 | 2003/0191082 A1 | 10/09/2003 | Wheeler | | | 03/19/2003 |
| | AB3 | 2003/0203863 A1 | 10/30/2003 | Hobart <i>et al.</i> | | | 04/23/2002 |
| | AC3 | 2004/0171572 A1 | 09/02/2004 | Wheeler | | | 12/30/2003 |
| | AD3 | 2004/0209241 A1 | 10/21/2004 | Hermanson <i>et al.</i> | | | 12/19/2003 |
| | AE3 | 2004/0162256 A1 | 08/19/2004 | Geall <i>et al.</i> | | | 12/02/2003 |
| | AF3 | 6,867,195 B1 | 03/15/2005 | Felgner <i>et al.</i> | | | 06/07/1995 |
| | AG3 | 6,875,748 B2 | 04/05/2005 | Manthorpe <i>et al.</i> | | | 04/23/2001 |
| | AH | | | | | | |
| | AI | | | | | | |
| | AJ | | | | | | |
| | AK | | | | | | |

FOREIGN PATENT DOCUMENTS

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|------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
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| | AR | <u>3</u> | Orizio, G., <i>et al.</i> , "Freeze-dried mannitol for injectable preparations using an automatic lyophilization cycle," <i>Boll. Chim. Farm.</i> 132:368-374, Società Editoriale Farmaceutica (1993) |
| | AS | <u>3</u> | Österberg, T., <i>et al.</i> , "Development of a Freeze-Dried Albumin-Free Formulation of Recombinant Factor VIII SQ," <i>Pharm. Res.</i> 14:892-898, Plenum Press (1997) |
| | AT | <u>3</u> | Todd, C.W., <i>et al.</i> , "Development of an adjuvant-active nonionic block copolymer for use in oil-free subunit vaccines formulations," <i>Vaccine</i> 15:564-570, Elsevier Science Ltd. (1997) |

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1530.0620001/EKS/JAHAPPLICATION NO.
10/725,009FIRST NAMED INVENTOR
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1645**U.S. PATENT DOCUMENTS**

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|---------------------|-----|--------------------|------|------|-------|-----------|-------------|
| | AA | | | | | | |
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| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|----------|--|
| | AR | <u>4</u> | Todd, C.W., <i>et al.</i> , "Systemic Development of a Block Copolymer Adjuvant for Trivalent Influenza Virus Vaccine," <i>Dev. Biol. Stand.</i> 92:341-351, Karger (1998) |
| | AS | <u>4</u> | Tse, C. and Capeau, J., "Quantification des acides nucléiques par PCR quantitative en temps réel," <i>Ann. Biol. Clin.</i> 61:279-293, John Libbet Eurotext (May-June 2003) |
| | AT | <u>4</u> | Wade, A. and Weller, P.J., eds., "Benzalkonium Chloride," "Benzethonium Chloride," "Cetrimide," in: <i>Handbook of Pharmaceutical Excipients</i> , American Pharmaceutical Association, Washington, DC, pp.27-31, 96-98 (1994) |

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| | FIRST NAMED INVENTOR Geall, A. | |
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| | AA | | | | | | |
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| | AH | | | | | | |
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|------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|--|
| | AR | 5 | Copy of Co-Pending U.S. Patent Application No. 09/478,457, Wolff et al., filed January 6, 2000 (NOT PUBLISHED) |
| | AS | 5 | Molina, M.C. <i>et al.</i> , "Maintenance of nonviral vector particle size during the freezing step of the lyophilization process is insufficient for preservation of activity: insight from other structural indicators." <i>J. Pharma. Sci.</i> 90:1445-1455, Wiley-Liss, Inc (October 2001) |
| | AT | 5 | Cherng, J.Y., "Stabilization of polymer-based gene delivery systems." <i>Int. J. Pharma.</i> 183:25-28, Elsevier B.V. (June 1999) |

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